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REMARKS

I. Introductory Comments

In the Office Action under reply, the Examiner rejected the claims as follows: under 35 U.S.C. §112, first paragraph, as allegedly failing to comply with the written description requirement (claims 1-30); under 35 U.S.C §112, second paragraph, for reasons of enablement (claim 22); under 35 U.S.C. §103(a) as allegedly being unpatenable over Rossling et al. (WO 97/19676) (claims 1-17, 20-30); and under 35 U.S.C. §103(a) as allegedly being unpatentable over Rossling et al. (WO 97/19676) in further view of Setterstrom et al. (U.S. Patent No. 6,410,056) (claims 18-19). The rejections are traversed for reasons provided below.

II. Amendments to Claims

Claims 1-5 and 7-30 were previously pending in the application. Claims 1, 9, and 22 have been amended. Original claim 6 has been restored as "previously presented" and claim 7 has been canceled without prejudice. No claims have been added. Consequently, claims 1-6 and 8-30 will be pending upon entry of the Amendment.

Support for the amendments is identified below. Additional support other than that identified below may exist in the specification for one or more amendments to the claims.

Claim 1 has been amended to delete certain language. In addition, claim 1 has been amended include the element recited in claim 7. As claim 7 represents an originally filed claim, the requisite support for element is satisfied.

Claim 6 was inadvertently canceled as this claim was erroneously believed to recite the subject matter incorporated into claim 1. Applicants have corrected this unintentional error by reintroducing claim 6 as "previously presented" and canceling claim 7, which does recite the subject matter now incorporated into claim 1.

A period (".") has been added at the end of claim 9 in order to provide proper syntax.

Claim 22 has been amended to delete the phrase "and derivatives." The change serves to improve the clarity of the claim.

As support for the claimed subject matter is found in the application as filed, no new matter is introduced by the entry of the above-identified changes to the claims. The changes to

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the claims are made for clarification purposes only and should not be interpreted as acquiescence in any claim rejection.

III. The Rejection Under 35 U.S.C. §112, First Paragraph

The Examiner objected to claims 1-30 under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. Specifically, the Examiner has taken the position that recitation of "selected such that the volume fraction of the surfactant phase is at least 0.6" is new and does not have support in the original disclosure.

In order to expedite prosecution of the present claims only, Applicant has deleted the specific phrase cited by the Examiner, thereby rendering the Examiner's rejection moot.

Applicant notes that claim 1 has been amended to recite "wherein the volume fraction of the surfactant phase is at least 0.60," which is exact language taken from dependent claim 7. As stated in the Manual of Patent Examining Procedure (M.P.E.P.), "[t]he claims as filed in the original specification are part of the disclosure." See M.P.E.P. §2163. Thus, the element recited in original claim 7 and now introduced into claim 1 via the present amendment has support in the original disclosure.

As each of the claims finds support in the original disclosure, reconsideration and removal of the rejection under 35 U.S.C. §112, first paragraph, is respectfully requested.

IV. The Rejection Under 35 U.S.C. §112, Second Paragraph

The Examiner maintained the rejection of claim 22 under 35 U.S.C. §112, second paragraph, for reasons of indefiniteness. Specifically, the Examiner has taken the position that the term "derivatives" is vague and indefinite. In response -- and only for purposes of expediting prosecution -- Applicant has deleted this term from the claim. As the term is no longer present in the claim, the Examiner's rejection has been rendered moot. Consequently, reconsideration and removal of the rejection under 35 U.S.C. §112, second paragraph, is respectfully requested.

V. The Rejections Under 35 U.S.C. §103(a)

The Examiner has rejected claims 1-17 and 20-30 under 35 U.S.C. §103(a) as being allegedly unpatentable over Rossling et al. (WO 97/19676). In addition, the Examiner rejected

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claims 18-19 as being allegedly unpatentable over Rossling et al. (WO 97/19676) in view of Setterstrom et al. (U.S. Patent No. 6,410,056).

In the Response dated December 22, 2003, Applicant argued that the Examiner failed to establish a *prima facie* case for obviousness. As will be appreciated by the Examiner, three basic criteria must be satisfied in order to form a *prima facie* case of obviousness. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art and not based on applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

In the December 22, 2003, Response, Applicant specifically pointed out, *inter alia*, that Rossling et al. failed to suggest (a) the optimal solubility parameters of the polymer solvent and the aqueous surfactant phase, and (b) a high volume fraction of surfactant phase. In addition, with respect to Setterstrom et al., Applicant pointed out that this cited reference does not describe or suggest the process of claim 1 and that no mention is made concerning the solubilities or surfactant phase volume fractions.

In the Examiner's *Response to Arguments* presented in the final Office Action, the Examiner argues that independent claim 1 of Rossling et al. teaches a polymer solution in a partially water miscible halogen-free solvent and that "it would be within the skill of the artisan in the microparticle art to optimize the volumes, and hence, solubility parameters, to achieve that recited in the instant claims." In addition, the Examiner has taken the position (a) that the arguments are not commensurate in scope with the independent claims, (b) that Rossling et al. teach the same polymer solvents and surfactants as taught in the instant dependent claims, and (c) that the claims of Rossling et al. are not limited to fractions below 0.6.

In response, Applicant initially wishes to point out -- contrary to the Examiner's assertion -- claim 1 of Rossling et al. specifically requires that the surfactant solution be present in the total volume in an amount *less than* 60% v/v. See corresponding U.S. patent of Rossling et al. (U.S. Patent No. 6,294,204) at column 10, lines 27-30. Furthermore, there is not a single

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example of or suggestion to use a volume fraction of the surfactant phase *greater than* at least 0.60 in a method for preparing microparticles in Rossling et al.

Furthermore, choosing to use a surfactant phase *greater than* at least 0.60 is not merely "discovering the optimum or workable ranges" when the cited art teaches a total volume in an amount *less than* 60% v/v. "Discovering the optimum or workable ranges" might involve, for example, discovering that 20% to 30% provides an optimum range. In the present case, however, Applicant determined that an amount outside the range taught and suggested by cited art provides a novel and non-obvious method. Thus, the Examiner's contention that the *presently claimed* range is neither taught nor suggested by the cited art is untenable. Thus, the third element of establishing a *prima facie* case of obvious -- that of the prior art reference (or references when combined) must teach or suggest all the claim limitations -- is not satisfied.

Moreover, in closely scrutinizing the claimed processes, other differences exist between the process encompassed by the pending claims and the process disclosed in Rossling et al. For example, the process encompassed by the pending claims requires one less step than the process disclosed in Rossling et al. Specifically, the process encompassed by the claims in the pending application results in microparticles "*produced upon addition of the surfactant phase*" whereas the process disclosed in Rossling et al. requires the removal of the solvent to form microparticles. Because Rossling et al. emphasizes the criticality of carrying out each an every step of its described process, there is simply no suggestion or motivation, either in the reference itself or in the knowledge generally available to one of ordinary skill in the art, to modify the reference to arrive at the claimed invention. Consequently, the first element for establishing a *prima facie* case of obvious -- that of providing the requisite suggestion or motivation -- is lacking.

In attempt to address the apparent deficiencies of Rossling et al. with respect to pending claims 18 and 19, the Examiner has cited Setterstrom et al. The process described in Setterstrom et al., however, is a very different process from both Rossling et al. and the instant claims. As a consequence, the Examiner's reliance of Setterstrom et al. does not remedy the deficiencies identified above with respect to Rossling et al.

Thus, for all of the above reasons, a *prima facie* case for rejecting the claims under 35 U.S.C. §103(a) has not been made by the Examiner. Consequently, reconsideration and removal of the rejection is respectfully requested.

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VI. Conclusion

In view of the foregoing, Applicants submit that the pending claims satisfy the requirements of patentability and are therefore in condition for allowance. Reconsideration and withdrawal of all objections and rejections is respectfully requested and a prompt mailing of a Notice of Allowance is earnestly solicited.

If a telephone conference would expedite the prosecution of the subject application, the Examiner is requested to call the undersigned at (650) 620-5506.

Respectfully submitted,
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